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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-----------------------|
| 09/937,908 | 01/07/2002 | Ivo Feussner | 213721 | 5676 |
| 23460 | 7590 | 01/30/2004 | EXAMINER | |
| LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780 | | | | MCELWAIN, ELIZABETH F |
| ART UNIT | | PAPER NUMBER | | |
| | | 1638 | | |

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/937,908 | FEUSSNER ET AL. |
| | Examiner | Art Unit |
| | Elizabeth F. McElwain | 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 and 26-46 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Specification

1. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.
2. The abstract of the disclosure is objected to because the lines are single spaced, making it difficult to read. Correction is required. See MPEP § 608.01(b).
3. The specification is objected to for failing to comply with the Sequence Rules. Figure 5 sets forth a sequence, however, no sequence listing has been provided. A computer readable form (CRF), as well as a paper copy and a letter stating that they are the same is required. See the attached page for directions regarding where to submit the sequence listing and CRF. Please note that number 3 is no longer available as an option, since Tech Center 1600 has relocated.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on September 28, 2001 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Election/Restrictions

5. Applicants' election with traverse of Group II, claims 21-25 in the paper filed November 12, 2003 is acknowledged. The traversal is on the ground(s) that the prior art does

not teach a plant LOX with altered position specificity, therefore there is a special technical feature linking the claimed inventions. Applicants argue that the references cited on page 1 of the specification disclose wild type plant and mammal LOX. This is not found persuasive because the prior art does teach a plant LOX with altered position specificity, as shown by the references cited in the specification on page 1 and that are disclosed in the IDS. See Feussner et al, Steczko et al and Hornung et al, for example.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-20 and 26-46 are withdrawn as drawn to the non-elected inventions.

Claims 21-25 are objected to for depending on non-elected base claims. Correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-25 are indefinite in that they all depend on claim 15, which recites that the claimed plant lipoxygenases would have altered position specificity relative to a wild-type plant lipoxygenase. Given that a wild type gene would be considered to be the gene that predominates in the wild population and there are many different plant species, which may each have a different plant lipoxygenase that is predominant in the wild population, it is

unclear what would be considered the wild type lipoxygenase in each instance. It is also unclear how this term would relate to a domesticated population. Therefore, it is unclear what the claimed plant lipoxygenase would have altered specificity relative to.

Claims 22-25 are also indefinite in that claims 16-19, on which they depend, recite specific regions where one or more amino acids are altered by reciting amino acid positions by numbered position. The claim recites that this sequence is a lipoxygenase from *Cucumis sativas*. However, the claims do not recite any particular sequence as a reference for these numbered positions. It is unclear if a lipoxygenase from *Cucumis sativas* would be one particular sequence, in which case the SEQ ID NO should be provided. However, if this is not the case, then it is unclear what sequences would represent a lipoxygenase from *Cucumis sativas* and how one would distinguish these sequences from lipoxygenase sequences from any other organism. Therefore, it is unclear what the base sequence is that is altered and it is unclear which amino acids may be altered and would be within the scope of these claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The claims are drawn to lipoxygenases that are obtained by the methods of claims 15-19, which require the substitution of one or more amino acids in a wild-type plant lipoxygenase to obtain a plant lipoxygenase with altered position specificity. Claims are also drawn to lipoxygenases produced by altering amino acids of a lipoxygenase from *Cucumis sativas* at specific numbered sites. However, the structure that would define lipoxygenase from *Cucumis sativas* has not been described, and therefore a written description of the claimed lipoxygenases with specific amino acids substituted is not provided. In addition, the specific structure intended for a wild-type plant lipoxygenase has not been disclosed, nor has the functional activity with regard to the position specificity. The only description of a complete structure of a lipoxygenase is the sequence provided in Figure 5, and lipoxygenases that have altered position specificity with respect to this sequence at the amino acid position 527 to 536 and/or 593 to 602.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

10. Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the lipoxygenase from *Cucumis sativas* that is set forth in Figure 5 that has amino acid substitutions in the region of amino acid position 527 to 536 and/or 593 to 602, does not reasonably provide enablement for any plant lipoxygenase that has altered position specificity relative to wild type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to lipoxygenases that are obtained by the methods of claims 15-19, which require the substitution of one or more amino acids in a wild-type plant lipoxygenase to obtain a plant lipoxygenase with altered position specificity. Claims are also drawn to lipoxygenases produced by altering amino acids of a lipoxygenase from *Cucumis sativas* at specific numbered sites. The specification has only provided a sequence of a lipoxygenase from *Cucumis sativas* that is set forth in Figure 5, and amino acid substitutions in the region of amino acid position 527 to 536 and/or 593 to 602. The specification does not disclose any other plant lipoxygenases that have been modified to have altered position specificity.

Steczko et al, (Biochemistry 31 (16) 4053-4057, 1992 in IDS) teach that substituting amino acids in a lipoxygenase can have unpredictable results, where numerous mutants were totally inactive, others had vastly reduced activity and others were insoluble. Therefore, the substitution of amino acids in a lipoxygenase can have a variety of effects other than altering position specificity. In addition, Feussner et al (FEBS Letters 367: 12-14, 1995 in IDS) teach a lipoxygenase from cucumber seedlings with unusual reaction specificity. Therefore,

lipoxygenases from plants can have a number of different specificities. However, the specification only teaches modifying this one enzyme with unusual reaction specificity, and only teaches that substituting amino acids in the region of amino acid position 527 to 536 and/or 593 to 602 will result in altered position specificity.

Given the unpredictability of the functional activity and specificity of a lipoxygenase that has amino acids substituted therein, as taught by Steczko; and given the variety of different reaction specificities present in plant lipoxygenases, as taught by Feussner et al; and given the lack of working examples other than the sequence of a lipoxygenase from *Cucumis sativas* that is set forth in Figure 5, and amino acid substitutions in the region of amino acid position 527 to 536 and/or 593 to 602; and given the absence of guidance with regard to the sequences of other plant lipoxygenases and their specificities, as well as the absence of guidance for modifying any other plant lipoxygenases and screening them for altered position specificities; and given the breath of the claims, which encompass any plant lipoxygenase with an altered position specificity relative to wild type; it would require undue experimentation by one skilled in the art to make and/or use the invention, as broadly claimed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Feussner et al (FEBS Letters 367: 12-14, 1995 in IDS).

The claim is drawn to a plant lipoxygenase that has altered position specificity relative to a wild type plant lipoxygenase.

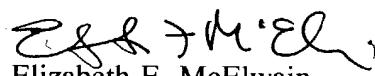
Feussner et al teach a plant lipoxygenase with unusual specificity, wherein this would be an altered specificity relative to what is normally found in a plant that would be considered wild type. And the particular method by which it is made would not impart different characteristics to the enzyme that would distinguish it from that taught by Feussner et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Elizabeth F. McElwain
Ph.D. Level Examiner
Art Unit 1638